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Brompheniramine Maleate and Pseudoephedrine Sulfate Oral Solution

» Brompheniramine Maleate and Pseudoephedrine Sulfate Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of brompheniramine maleate ($C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$) and pseudoephedrine sulfate [$(C_{10}H_{15}NO)_2 \cdot H_2SO_4$].

USP Reference standards ⟨11⟩—
USP Brompheniramine Maleate RS
USP Pseudoephedrine Sulfate RS

Identification—

A: The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

B: A solution of it meets the requirements of the test for *Sulfate ⟨191⟩*.

C: Transfer a volume of Oral Solution, equivalent to about 6 mg of brompheniramine maleate, to a separator, add 0.5 mL of ammonium hydroxide and 5 mL of methylene chloride, shake for 1 minute, and allow the layers to separate. Use the clear, lower layer as the test solution. Prepare separate Standard solutions in methanol containing, respectively, 1.2 mg of USP Brompheniramine Maleate RS and 9 mg of USP Pseudoephedrine Sulfate RS per mL. Separately apply 5 µL of each solution to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of ethyl ether, methanol, and ammonium hydroxide (16:3:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by examination under short-wavelength UV light: the R_F values of the two principal spots obtained from the test solution correspond to those obtained from the Standard solutions.

Uniformity of dosage units ⟨905⟩—
FOR ORAL SOLUTION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩—
FOR ORAL SOLUTION PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

Assay—

Mobile phase—Prepare a mixture of water, acetonitrile, methanol, and tetrahydrofuran (550:320:80:50). Transfer 1.0 mL of phosphoric acid, followed by 4.33 g of dodecyl sulfate sodium to this mixture, and mix. Adjust with ammonium hydroxide to a pH of 3.50 ± 0.05, filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*). [NOTE—The pH of the *Mobile phase* is critical and may cause 1 to 4 minutes of differences in the retention times of internal standard and brompheniramine maleate.]

Internal standard solution—Transfer about 50 mg of naphazoline hydrochloride to a 100-mL volumetric flask, add *Mobile phase* to volume, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Brompheniramine Maleate RS in *Mobile phase,* and quantitatively dilute with *Mobile phase* to obtain a solution having a known concentration of about 6000*J* µg per mL, *J* being the ratio of the labeled amount, in mg, of brompheniramine maleate to the labeled amount, in mg, of pseudoephedrine sulfate per mL *(Solution P).* Transfer about 30 mg of USP Pseudoephedrine Sulfate RS, accurately weighed, to a 25-mL volumetric flask, add 5.0 mL each of *Solution P* and *Internal standard solution,* dilute with *Mobile phase* to volume, and mix to obtain a *Standard preparation* having known concentrations of about 1200*J* µg of USP Brompheniramine Maleate RS per mL and about 1.2 mg of USP Pseudoephedrine Sulfate RS per mL.

Assay preparation—Using a "To contain" pipet transfer an accurately measured volume of Oral Solution, equivalent to about 30 mg of pseudoephedrine sulfate, to a 25-mL volumetric flask. Rinse the pipet with about 5 mL of *Mobile phase,* collecting the rinse in the volumetric flask. Add 5.0 mL of *Internal standard solution,* dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L11. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 1.0 for pseudoephedrine sulfate, 1.5 for naphazoline hydrochloride, and 2.5 for brompheniramine maleate; the resolution, *R,* between the pseudoephedrine sulfate and naphazoline hydrochloride peaks is not less than 3, and between the brompheniramine maleate and naphazoline hydrochloride peaks is not less than 3; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of brompheniramine maleate

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($C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$) in each mL of the Oral Solution taken by the formula:

$$25CV(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Brompheniramine Maleate RS in the *Standard preparation; V* is the volume, in mL, of Oral Solution taken; and R_U and R_S are the peak response ratios obtained for brompheniramine maleate and naphazoline hydrochloride from the *Assay preparation* and the *Standard preparation,* respectively. Calculate the quantity, in mg, of pseudoephedrine sulfate $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$ in each mL of the Oral Solution taken by the same formula, changing the terms to refer to pseudoephedrine sulfate.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE ORAL SOLUTION	Documentary Standards Support Associate Scientific Liaison.	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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